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Mail: FDA Dockets Management Branch
(HFA-305) Food & Drug Administration
Attn: Michael Friedman, M.D.
Lead Deputy Commissioner
5630 Fishers Lane, Room 106
Rockville, Maryland 20857

2544 '98 SEP -3 P12:22

Dear Dr. Friedman:

I am writing in regard to the following proposed FDA regulations:

21 C.F.R. 101.93 (II)(B)

21 C.F.R. 101.93 (I)

21 C.F.R. 101.93 (g)(2)(ii), (v), (vi), (vii), (viii).

I am categorically opposed to the enacting of these regulations as law because they would interfere with my right to receive valuable information about dietary supplements. It is my understanding that under the proposed regulations:

1. Claims for states/symptoms not typically considered 'diseases', such as aging, pregnancy and menopause, would be prohibited for dietary supplements, even where there is scientific substantiation to support them.

2. A dietary supplement for which only structure/function claims are made in the label or labeling in accord with section 403(r) of the act may nevertheless be subject to regulation as a drug if the agency has other evidence that the intended use of the product is for the diagnosis, cure, mitigation, treatment, or prevention of a disease.

3. Labeling of dietary supplements could not refer to or cite titles of publications (including scientific journals) in labeling of dietary supplements if the title mentions a disease.

4. Representations that a dietary supplement is useful to supplement drug therapy or has any role in the body's response to a disease would be prohibited (even where there is scientific support).

While I acknowledge that appropriate agency guidelines on the use of structure/function claims is necessary, the proposed regulations go beyond public protection. They are meant to control something over which I should have the freedom to exercise my own judgment and intelligent reasoning. It is essential to those who take full responsibility for their own healthcare to have access to valuable and accurate information on vitamins, minerals and herbs regarding the maintenance of wellness and the prevention of disease.

Please reconsider and revise these proposed regulations so that we can continue to receive valuable information necessary to make well-informed health decisions.

Sincerely,

Name and Address:

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